

## **REMARKS**

Claims 1-13 and 26 are pending. Claims 2, 5 and 11 have been cancelled. Claims 27-30 are newly added. Claims 14-26 have been withdrawn from consideration.

### **Rejections under 35 U.S.C. §112, second paragraph**

Claim 4 has been rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicants traverse the rejection as applied to the claims as amended.

Claim 4 has been amended to correct a typographical error. The term “the said adjuvant” now reads “the adjuvant”. Applicants respectfully request withdrawal of this rejection.

### **Rejections under 35 U.S.C. §102**

Claims 1-9 and 11-13 have been rejected under 35 U.S.C. §102(b) as being anticipated by Duncan *et al.* (WO 94/20070 published September 15, 1994, “Duncan”). Applicants respectfully traverse the rejection.

Duncan discloses vaccine compositions using polymeric mucoadhesives to deliver an antigen. Adjuvants are optionally included in the composition. Duncan does not disclose using particulate vaccines with the claimed adjuvants.

Claim 1 has been amended to recite a method for enhancing the effect of a vaccine by administering particulate vaccines. The only reference to particulate vaccines in Duncan is in the background section of the patent on page 2. Duncan describes how in the past, antigens incorporated into microparticles, nanoparticles or liposomes may be more immunogenic than free antigens, and speculates that this was because they may be trapped in the mucous. Duncan discloses that instead of using particles, one could utilize mucoadhesives. This is clear, for example from the disclosure on page 14, lines 14-18, which stresses that the compositions should be simple combinations of immunogens, mucoadhesive and adjuvant. The remainder of the disclosure, including that which the Examiner describes on pages 9-10 should be read in that light.

Claims 1-13 have been rejected under 35 U.S.C. §102(e) as being anticipated by Griffin, K.F. *et al.* 1998 (*Vaccine* 16(5):517-521, “Griffin”). Applicants respectfully traverse the rejection.

The Examiner appears to be asserting that the poly(L)lactide disclosed in Griffin is an adjuvant. Claim 1 of the present application specifically lists different classes of antigens denoted A) to H). Applicants respectfully submit that poly(L)lactide is not encompassed in the classes of adjuvants listed in the claims of the present application and poly(L)lactide is not positively charged as recited in class C). Therefore, this polymer does not fall within the definitions of any of classes A) to H) of Claim 1.

Similarly, the “second adjuvant” which the Examiner refers to as being disclosed in Griffin *et al.* is not encompassed by the claims of the present application. IFN- $\gamma$  does not fall within any of the adjuvant classes (A) to (H) in claim 1. Griffin does not describe any component which could be within the claimed classes of adjuvants (A) to (H) and therefore does not anticipate the present claims.

Claims 1-13 have been rejected under 35 U.S.C. §102(e) as being anticipated by Park *et al.* (United States Patent No. 6,267,987 B1 published July 31, 2001 with earliest filing date of December 11, 1998, “Park”). Applicants respectfully traverse the rejection.

Park discloses certain block co-polymers for use as carriers for pharmaceuticals. However Park simply suggests that these polymers are an “all purpose” carrier for an enormous range of drugs or other therapeutic agents. No adjuvant or immunostimulant properties are disclosed in this reference. Similarly, the block co-polymers described in Park fail to fall within the classes of adjuvants A) to H) listed in the claims. Therefore, Park does not anticipate the claimed method.

The properties illustrated in the specification clearly show that the novel adjuvants have unexpected advantages when used in combination with specific immunogens in vaccines. This is not disclosed or taught in any way by Park.

### **Claim Objections**

Claim 4 has been objected to because of an informality where the claim contains the typographical error "the said adjuvant". As mentioned above, applicants have amended Claim 4 to read "the adjuvant" and respectfully request withdrawal of this objection.

### **CONCLUSION**

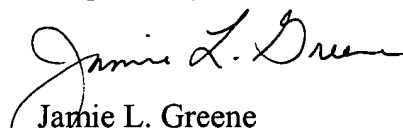
Applicants respectfully submit that this is a complete response to the Office Action dated May 24, 2004, and that the pending claims are definite, satisfy the written description requirement, are enabled, and are novel.

A check for a two month petition for extension of time is included herewith. The Commissioner is hereby authorized to charge any deficiency, or credit and over payment to Deposit Account No. 11-0855.

Early and favorable consideration is earnestly solicited. If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's amendment, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Allowance of the claims is respectfully solicited.

Respectfully submitted,

  
Jamie L. Greene  
Reg. No. 32,467

KILPATRICK STOCKTON LLP  
1100 Peachtree Street  
Suite 2800  
Atlanta, Georgia 30309-4530  
Tel. (404) 745-2473  
Attorney Docket No. 41577/263898